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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,265	12/03/2001	Masatsugu Maeda	06501-096001 / C2-105DP1P	5055

26161 7590 12/21/2005

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EXAMINER	
RIGGINS, PATRICK S	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,265	MAEDA ET AL.	
	Examiner	Art Unit	
	Patrick S. Riggins	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *9-19 and 28-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of an amendment filed 9/14/05. Claims 1 and 2 were amended. New claims 20-31 were added. Presently claims 1-31 are pending, with claims 9-19 and newly entered claims 28-31 withdrawn pursuant to the restriction requirement of record. Claims 1-8 and 20-27 are presently under examination.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See the line bridging pages 55 and 56 of the specification.

Claim Objections

3. Claims 20-23 are objected to because of the following informalities: claim 20 recites that the isolated nucleic acid "comprises a coding region". In the broadest reasonable interpretation, this necessarily includes any sequence that is found in the coding region of the recited sequences. As such, nearly any sequence in the prior art is applicable against claim 20, and those claims that depend from claim 20. It would be remedial to instead recite –comprises the coding region--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by the amendment to the claims on 9/14/05.

6. Claim 1 recites "any one of SEQ ID NOs: 2, 4, and 17". This does not make sense grammatically. It is appropriate to list items with "and " if the recitation is in proper Markush format. However, as the claim is simply drawn to a selection of alternatives, "or" is appropriate. Thus it would be remedial to change "and" to --or--.

7. Claims 2, 20, and 24 each have the same problem as delineated above for claim 1.

8. Each of the remaining rejected claims depend from claims 1, 2, 20, or 24 and none of these dependent claims correct the deficiency noted, therefore each is similarly rejected as vague and indefinite.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-8 and 20-27 stand rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. When assessing utility, one is to consider if the claimed invention possesses a specific and substantial utility and if so, if that utility is credible. Applicant has not

disclosed any specific and substantial utility or a well-established utility for the claimed invention.

11. Each of the claims is drawn to a nucleotide sequence that encodes an NR10 isoform or a vector or transformant containing the nucleic acid. For a nucleic acid to have utility, it must have an asserted utility that is specific, substantial, and credible. On pages 56 and 56, the specification has a variety of statements regarding the utility of the claimed sequences. Each of these claims is purely speculative in nature with no evidence of record to support any of these asserted utilities.

12. It is further noted that each of the asserted utilities in this section are exceptionally broad and thus fail to identify any specific role for NR10. It is first asserted that "the proteins of this invention can be applied for diagnosis and treatment of diseases related with immunity and hematopoiesis" (page 56, lines 26-28). This is purely speculative and does not reach the level of a specific utility. There is no identification of any particular disease that NR10 may play some role in. There are a vast array of different hematopoietin receptors as discloses on pages 1 and 2 of the specification. Without identifying a particular disease or diseases that NR10 can be used to diagnose or treat, there has been no establishment of a specific utility in this case.

13. Additionally, the simple identification that NR10 is a hematopoietic receptor does essentially nothing to suggest a function for NR10. To be in the hematopoietin receptor family is to be in a very broad family that has many members with varying functions. "cytokines represent a diverse group of molecules that collectively exert a wide range of actions (reference omitted). The term cytokine is rather general, technically referring to a molecule made by one cell that acts on another" (J Biol Chem 277: 29355-29358, newly cited, page 29355, column 1, first three lines).

14. It is next asserted that NR10 would be useful for identifying a novel hematopoietic factor. It is asserted that "cellular immunity or hematopoietic function *in vivo* will be enhanced" (sentence bridging pages 56 and 57). It is then asserted that drugs could be developed for promoting proliferation of differentiation of immune cells and that the drugs could be useful for enhancing cytotoxic immunity against "particular types of tumor cells" (page 57, line 6). In the case of the last assertion, there is no evidence to suggest that NR10 plays any role in tumor immunity and this assertion is purely speculative. Additionally, there is no identification of any particular type of tumor cells that may be treated with the NR10 agonists. Regarding the first assertion identified in this paragraph, it is wholly unclear how this assertion could be more broad. What types of cells will the NR10 agonist affect? Will the agonistic agents serve to promote proliferation or block proliferation? Indeed if there is no effect on proliferation clearly then the agent is acting to aid in differentiation. In short what other option is there aside from effects on proliferation or effects on differentiation? Clearly this series of assertions fails to establish a specific utility.

15. Next there is the assertion that inhibitors could be identified that would inhibit function of NR10. This is merely a redundant assertion that has essentially no meaning, as there has been no function assigned to NR10. Therefore how could one expect to even know if NR10 were being inhibited? The inhibitors are the asserted to be useful for suppressing cellular immunity or inhibiting cellular proliferation. There is no evidence at all to suggest any role of NR10 to enhance or promote immune function or cellular proliferation. There is nothing to suggest that by inhibiting NR10 function one would be able to inhibit an immune response. Indeed there is nothing to suggest what function NR10 even possesses that would even allow someone to

identify an agent that would inhibit. Indeed what would the nature of the inhibition be? The specification provides no answers.

16. Finally it is asserted that these putative inhibitors could act to suppress autoimmunity, prevent tissue rejection, to treat diseases caused by abnormal upregulation of the immune response, and to treat allergies. In making these assertions, applicants have essentially stated that these inhibitors could possibly treat any problem that arises in the immune system. This is the antithesis of a specific utility. By making this series of statements, applicants are essentially setting the field such that if a function were later discovered for NR10, that one would be able to argue that this function had previously been asserted. Again there is no identification of any particular disease that NR10 may be implicated in. By essentially stating all possible problems with the immune system, the widest possible net relating to immune regulation has been cast.

17. It is again noted, that these assertions, identified in the above paragraphs, all are presented in a prophetic fashion, confirming that at the time of filing the applicants did not yet have any concrete evidence regarding a specific utility for NR10. Thus throughout, statements such as, things are expected or thought to be involved in the utility of NR10. These are all prophetic and would seem to clearly establish that the applicants were unaware of a specific utility at the time of filing. Again it seem quite clear upon reading of the specification that the inventors were not aware of any specific or substantial utility and thus were unable to properly assert a utility that would meet the requirement of 35 U.S.C. 101.

18. It is further noted that claims 5-8, 22, 23, 26, and 27 are drawn to a transformant harboring the nucleic acids or vectors of the invention. As there is no utility for the nucleic acids there is no utility for the transformants. The specification details a variety of methods for

producing the proteins of the invention, however the breadth of the transformants includes such things as humans. Is quite clear that there is no utility in expressing a protein from, for example a human. The only utility in this regard are the standard methods for protein expression as detailed at the bottom of page 17 and the middle of page 19 through page 21.

Response to Arguments

19. Applicant's arguments filed 9/14/05 have been fully considered but they are not persuasive. Applicant asserts that the specification does indeed disclose specific and substantial utilities. As addressed in paragraphs 15-20 above, none of the assertions present in the specification rise to the level of being specific. These assertions are indeed substantial as control of the immune response is legitimate goal, But by broadly listing essentially every possible effect a hematopoietin receptor cold haye, nowhere does the specification point to any specific utility. Any member of the hematopoietin or cytokine receptor family could theoretically perform indeed the asserted utilities. So aside from failing to identify a specific utility in this regard, there also has been no identification as to why NR10 would have a specific function. With such broad recitation of utility that could be performed by a variety of different molecules there is no asserted specific utility.

20. Applicant then argues that the asserted utilities are also credible because NR10 belongs to the hematopoietin receptor family. As stated above this is a very broad family with a variety of different functions. The lack of credibility does not derive from a disbelief that NR10 is a member of this family, but rather a disbelief that NR10 would play a role in essentially every possible place that immune cells can become disregulated. No function has been ascribed to

NR10. Yes, NR10 may potentially bind to a novel hematopoietin factor, but there is no evidence of record to show that NR10 interacts with anything in this regard. With no utility established for NR10 there can be no utility for an unidentified ligand. Even if NR10 does bind to a hematopoietin factor, without any knowledge of a function for the receptor or the ligand, there is no evidence of a utility for the putative ligand. Thus the ability to bind to a putative ligand offers no indication as to a utility for the proteins.

21. The specification fails to establish any evidence that NR10 is associated with any disease state or immune function. Absent this evidence, there is no way to ascertain from the specification what utility may be ascribed to NR10.

22. Applicant then argues that three papers, submitted properly in an Information Disclosure Statement provide support for the asserted utilities of the specification. Both Dillon and Diveu are post filing art that have apparently independently identified NR10 or NR10-related proteins. Both Dillon and Diveu would seem to provide support, however, as the information they disclose is considerably after the effective filing date of this application any teachings one may glean from either Dillon or Diveu are irrelevant as these teachings were not available to the skilled artisan at the time of filing. The third paper by Kernebeck, addresses the function of gp130 and as such is irrelevant with regard to the distinct protein NR10. Therefore the information provided by Kernebeck is immaterial to the issues at hand.

23. Applicant then argues that NR10 has a well-established utility. As NR10 is an apparently novel protein with only limited homology to a very broad class of receptors there is clearly not any well-established utility.

24. Claims 1-8 and 20-27 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

25. Applicant's arguments filed 9/14/05 have been fully considered but they are not persuasive. Applicant simply argues that the arguments presented regarding the 101 rejection are also applicable to the lack of enablement rejection. From the ejection and arguments above, the utility rejection has been maintained. Thus this line of argument is moot.

Conclusion

26. No claim is allowed.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1633

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER